UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,694	10/02/2003	Nader Najafi	IB-8	9770

27127 7590 05/09/2008

HARTMAN & HARTMAN, P.C.
552 EAST 700 NORTH
VALPARAISO, IN 46383

EXAMINER
MALLARI, PATRICIA C

ART UNIT	PAPER NUMBER
3735	

NOTIFICATION DATE	DELIVERY MODE
05/09/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

domenica@hartmaniplaw.com
gayle@hartmaniplaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/677,694	NAJAFI ET AL.	
	Examiner	Art Unit	
	PATRICIA C. MALLARI	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,17-31,33-40,44,48-58,60-63,65 and 67-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *31* is/are allowed.

6)☒ Claim(s) *1-14,17-30,33-40,44,48-58,60-63,65 and 67-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 June 2007* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/6/08,2/7/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is a non-final Office action. The indicated allowability of claims 61 and 66 (the subject matter of which is incorporated into claim 2) is regretfully withdrawn. See the rejections below for details.

Response to Amendment

The amendment filed 6/6/07 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: New figure 7 shows an embodiment of a closed-loop pacing/ICD tuning system comprising an reader 104, 202, a power unit 107, and a pacing/ICD unit 106, wherein the reader receives data from the implant and transmits it to the pacing/ICD unit, the power unit provides power to the implant, and the pacing/ICD unit interrogates the implant. There is no support in the originally filed disclosure for such an embodiment. Page 11 of the instant specification presents four embodiments of the closed-loop pacing/ICD tuning system:

1) the pacing/ICD unit directly interrogates the implant

2) the pacing/ICD unit directly interrogates the implant and an external unit transmits power to the implant

3) an external reader receives data from the implant and transmits the data to the pacing/ICD unit

4) both the external reader and the pacing/ICD unit interrogate and/or power the sensor.

In none of these disclosed embodiments is there both an external reader and a power unit, as shown in figure 7.

The applicants are required to cancel the new matter in reply to this Office Action.

Rejections under 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 4, 7, 8, 10, 13, 14, 18, 22, 24, 26, 28, 30, 35, 36, 39, 40, 49-56, 58, 61 65, 67, 68, 71, and 72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 2 recites a system comprising at least one sensing device, a non-implantable readout device or electromagnetic telecommunication with and electromagnetic wireless powering of the sensor. and external unit operable to transmit power to the sensing device, and a pacing/ICD unit that interrogates the sensing device. Page 11 describes an embodiment in which the system is part of a closed-loop pacing/ICD tuning system. This embodiment fails to

address the combination of both the non-implantable readout device, as claimed, and the external unit. Page 11 describes that in a closed-loop pacing/ICD tuning system, the sensor is interrogated by the pacing/ICD unit and powered by an external unit. Alternatively, both the external reader and the pacing/ICD unit may interrogate and/or power the sensor. However, in none of the disclosed embodiments of the closed-loop pacing/ICD tuning system is there disclosed the addition of a non-implantable readout device in addition to the external unit and the pacing/ICD unit, as claimed. Therefore, the originally filed disclosure lacks sufficient description of a system comprising at least one sensing device, a non-implantable readout device or electromagnetic telecommunication with and electromagnetic wireless powering of the sensor. and external unit operable to transmit power to the sensing device, and a pacing/ICD unit that interrogates the sensing device, as claimed.

Claim 61 recites the sensing device being interrogates by a pacing/ICD unit and powered by an external unit. Claim 61 depends from claim 1 which recites a non-implantable readout device for at least one of electromagnetic telecommunication and electromagnetic wireless powering of the sensor. As discussed above, the specification lacks description of an embodiment comprising a sensor, a pacing/ICD unit, an external unit, and a non-implantable readout unit, as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5, 6, 9, 11, 12, 19, 21, 23, 25, 27, 29, 37, 38, 57 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,409,674 to Brockway et al. in view of US Patent No. 6,309,350 to Van Tassel et al. Brockway discloses a system for monitoring at least one physiological parameter for diagnosis of congestive heart failure within a patient, the system comprising at least one sensing device 305 capable of being implanted in a septum of the patient's heard and of monitoring the physiological parameter in a cavity of the patient's cardiovascular system. The sensing device comprises an anchoring mechanism, at least one sensor, and an inductor coil (see entire document, especially figs. 1, 3A-3D; col. 8, line 10-col. 10, line 25 of Brockway). The anchoring mechanism comprises first and second portions 312D separated by the sensor 305 (see entire document, especially fig. 3D of Brockway). The first portion is capable of passing through an opening of the septum and of expanding on a distal side of thereof within the heart cavity. The second portion is also adapted to expand on an oppositely-disposed proximal side of the septum such that the sensor is disposed relative to the anchoring mechanism and within the opening in the septum, the first portion and majority of the sensing device are located on the proximal side of the septum. The sensing device has a minimum protrusion to minimize the risk of thrombogenicity, with respect to a device configured for a larger amount of protrusion, or a larger device. The sensor is configured to monitor the physiological parameter within the heart cavity (see entire document, especially fig. 3D col. 8, lines

38-57 of Brockway). The anchoring mechanism of Brockway lacks the first and second portions being configured to clamp the septum there between when so implanted in an opening of a septum.

However, Van Tassel disclose an anchoring mechanism for an implantable sensor, comprising first and second portions, wherein the first portion is capable of passing through and opening in the septum and expanding on the distal side thereof within the heart cavity. The second portion is also adapted to expand on an oppositely-disposed proximal side of the septum such that the first and second portions are configured to clamp the septum there between (see entire document, especially fig. 3; col. 4, lines 1-17 of Van Tassel). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the anchoring mechanism of Van Tassel in place of that of Brockway, as it would merely be the substitution of one anchoring mechanism for another.

Regarding claims 5 and 6, the sensing device includes a battery, and the battery is rechargeable using wireless means (see entire document, especially col. 9, line 64-col. 10, line 14 of Brockway).

Regarding claims 9 and 23, the at least one physiological parameter includes pressure (see entire document, especially col. 7, lines 12-27 of Brockway).

Regarding claims 11 and 25, the applicants should note that the type of pressure sensed, as listed in claim 11, are merely a result of the location of the implantation of the sensing device. Therefore, the pressure types are merely “intended use” language, being reliant upon the intended use, since the intended location of the implantation is

intended use. This language cannot be relied upon to define over the prior art, since the prior art teaches all of the claimed structural limitations and their recited relationships. The device of Brockway, as modified, is certainly capable of being implanted in such a location so as to monitor or sense the listed pressures. Additionally, the sensing device may be located in any one of the chambers of the heart such that right or left atrial or ventricular pressure may be sensed (see entire document, especially col. 7, lines 14-37 of Brockway).

Regarding claim 12, the system calculates the change of pressure over time (dp/dt) (see entire document, especially col. 1, lines 30-55; col. 9, lines 33-41 of Brockway).

Regarding claim 19, a passive scheme is used to couple the sensing device and readout device (see entire document, especially col. 9, line 64-col. 10, line 25 of Brockway).

Regarding claim 21, an active scheme is used to couple the sensing device and readout device, in that the readout device must be actively brought into the vicinity of the sensing device in order to enable wireless powering and/or communication between the readout device and sensing device (see entire document, especially col. 9, line 64-col. 10, line 14 of Brockway).

Regarding claims 27 and 29, the applicant should note that the intended use of the invention cannot be relied upon to define over the prior art since the prior art teaches all of the claimed structural elements and their recited relationships. The system of Brockway may certainly be used for disease management or treatment, for

example (see entire document, especially col. 14, lines 37-40 of Brockway), or portable or ambulatory monitoring.

Regarding claims 37 and 38, the sensing device 105 is implanted using a minimally invasive outpatient technique or catheter delivery method (see entire document, especially col. 11, line 65-col. 13, line 54 of Brockway).

Regarding claim 57, the sensing device is augmented with at least a pacing device, voltage source or current source (see entire document, especially figs. 4 & 5, col. 9, line 64-col. 10, line 14of Brockway)

Regarding claim 69, at least a portion of the implantable sensing device is coated with at least one layer of coating material (see entire document, especially col. 8, lines 34-36 of Brockway).

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway in view of Van Tassel as applied to claims 1, 5, 6, 9, 11, 12, 19, 21, 23, 25, 27, 29, 37, 38, 57 and 69 above, and further in view of US Patent No. 6,120,457 to Coombes et al. Brockway describes the pressure sensor as being, in one embodiment, resistive, rather than capacitive (see entire document, especially col. 9, lines 30-42 of Brockway). However, Coombes teaches that an implantable pressure sensor may be capacitive or resistive (see entire document, especially col. 1, lines 21-30 of Coombes). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a capacitive sensor in place of the resistive sensor of Brockway, as modified, since

Coombes teaches capacitive and resistive pressure sensors to be functionally equivalent.

Claims 3, 17, 33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway in view of Van Tassel, as applied to claims 1, 5, 6, 9, 11, 12, 19, 21, 23, 25, 27, 29, 37, 38, 57 and 69 above, and further in view of US Patent No. 4,114,606 to Seylar. Brockway is silent as to the details of the scheme of inductive powering/communication between the sensing device and readout device. However, Seylar discloses inductive coupling between an implanted capacitive pressure sensor device and an external readout device wherein a resonant scheme is employed (see entire document, especially fig. 3; col. 3, line 61-col. 4, line 8; col. 4, line 30-col. 6, line 17 of Seylar). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the scheme of Seylar as that of Brockway, as modified, since Brockway, as modified, teaches using an implantable sensing device to sense pressure and an external readout device inductively coupled to the sensing device, and Seylar describes an appropriate means for coupling such devices. Alternatively it would have been obvious to one of ordinary skill in the art to use the type of system described by Seylar to sense pressure and transmit information in place of that of Brockway, as it would merely be the substitution of one known means for sensing pressure within a body and transmitting the information for another for the predictable result of transmitting measured pressure data.

Regarding claims 33 and 34, the readout device includes a barometric pressure sensor, wherein the barometric pressure sensor is adapted to compensate for variations in atmospheric pressure (see entire document, especially col. 7, lines 40-58 of Seylar)

Claims 44 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway in view of Van Tassel, as applied to claims 1, 5, 6, 9, 11, 12, 19, 21, 23, 25, 27, 29, 37, 38, 57 and 69 above, and further in view of US Patent No. 5,853,422 to Huebsch et al. Brockway, as modified, lacks the first and second portions comprising two opposing umbrella-shaped structures. Huebsch discloses an anchoring mechanism comprising first and second portions, wherein each portion comprises an opposing umbrella shaped structure (see entire document, especially fig. 24 of Huebsch). Therefore, it would have been obvious to use replaced the first and second portions of Brockway, as modified, with those of Huebsch, in order to further ensure securement of the first and second portions during implantation (see entire document, especially col. 7, lines 26-37 of Huebsch). Alternatively, it would have been obvious to one of ordinary skill in the art to replace the shape of the first and second portions of Brockway, as modified, with that of Huebsch, as it would merely be the substitution of one known shape for anchoring means for another.

Regarding claim 48, the anchoring mechanism may be made from nitinol, biocompatible metal, or polymer (see entire document, especially col. 3, line48- col. 4, line 10 of Huebsch).

Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway and Van Tassel, as applied to claims 1, 5, 6, 9, 11, 12, 19, 21, 23, 25, 27, 29, 37, 38, 57 and 69 above, and further in view of Brockway. Brockway, as modified, lacks the sensing device being directly interrogated by a pacing/ICD unit. However, Brockway discloses a second embodiment wherein the implanted sensing device 105 is interrogated directly by the pacing/ICD unit 400 wherein the embodiment of figure 54 may be combined for communication with any one or more external remote receivers (see entire document, especially fig. 5; col. 11, lines 28-62 of Brockway). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the second embodiment of Brockway with Brockway, as modified, since the second embodiment of Brockway is disclosed as capable of being combined for communication with any one or more external remote receivers (see entire document, especially fig. 5; col. 11, lines 28-62 of Brockway).

Claims 62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway in view of Van Tassel, as applied to claim 60 above, and further in view of US Patent No. 5,558,640 to Pfeiler. Brockway, as modified, teaches the pacing/ICD unit directly interrogating the sensing device, rather than the sensing device transmitting data to the readout device, which retransmits data to the pacing/ICD unit. However, Pfeiler teaches a system wherein an implantable sensing device 9 transmits data to an external readout device 15, which retransmits data to an implantable medical device 11 (see entire document, especially fig. 1; col. 3, line 63-67 of Pfeiler) and wherein the

implantable sensing device communicates directly with the implantable medical device (see entire document, especially col. 4, line 66-col. 5, line 9 of Pfeiler). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the communication scheme of Pfeiler in place of that of Brockway, as modified, as it would merely be the substitution of one known communication scheme for another, to yield the predictable result of the data being transmitted from the sensing device to the readout device and data being transmitted from the readout device to the pacing/ICD unit.

Regarding claim 63 and 68, the readout device and pacing/ICD unit perform at least one function of interrogation or powering of the at least one sensing device (see entirety of all documents, especially col. 9, line 45-col. 10, line 25 of Brockway; col. 3, lines 63-67; col. 4, line 66-col. 5, line 9 of Pfeiler).

Claim 70 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway in view of Van Tassel, as applied to claims 1, 5, 6, 9, 11, 12, 19, 21, 23, 25, 27, 29, 37, 38, 57 and 69 above, and further in view of US Patent No. 5,067,491 to Taylor, II et al. Brockway lacks a coating, as recited in claim 70. However, Taylor, II teaches an implantable pressure sensor, wherein at least the sensing portion of the sensor is coated in a thin layer of parylene (see entire document, especially col. 2, line 27-col. 3 of Taylor, II). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the coating of parylene of Taylor, II on the sensing portion of the sensing device of Brockway, as modified, in order to extend the life of the

sensor by protecting the implant form damage by body fluids (see entire document, especially col. 1, line 47-22; col. 2, line 57-col. 3, line 7 of Taylor, II).

Response to Arguments

Applicant's arguments with respect to claims 1, 5, 6, 9, 11, 12, 19, 21, 23, 25, 27, 29, 37, 38, 44, 57, and 69 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

Claim 31 is allowed. The allowability of claim 31 was addressed in previous Office actions filed 11/2/05 and 8/14/06.

No statement of allowability is being given at this time for claims 2, 4, 7, 8, 10, 13, 14, 18, 22, 24, 26, 28, 30, 35, 36. 39, 40, 49-56, 58, 61 65, 67, 68, 71, and 72 in light of the rejection under 35 U.S.C. 112, 1st paragraph, set forth above. Upon resolution of the 112 issues, the prior art will be revisited. However, is the prior art of record fails to teach or fairly suggest a system having a sensing device, non-implantable readout device, external unit, and pacing/ICD unit, wherein the readout unit allows electromagnetic telecommunication and/or wireless powering of the sensor, the pacing/IC unit at least interrogates the sensing device, and the external unit powers the device, in combination with all of the other limitations of the claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PATRICIA C. MALLARI whose telephone number is (571)272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/
Examiner, Art Unit 3735